

REMARKS

Rejection under 35 U.S.C § 102 – Anticipation

The Examiner issued a 35 U.S.C § 102(b) rejection of claims 1, 2, 6, 9-11, 14, 17, 18 and 20 as being anticipated by U.S. Pat. No. 5,865,723 to Love (Love). Specifically, the Examiner asserted that the Love reference teaches all the elements of Applicants' claims because it is clear from the figures of Love that the distal and proximal ends of the stent coincide with the distal and proximal ends of the tissue graft, respectively.

Applicants disagree with the Examiner's rejection because the cited reference does not teach, show or even suggest all the elements of Applicants' claims.

Specifically, the text of the specification of the Love reference does not teach stent tissue graft prostheses that include a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent; and a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent, wherein ***the first distal stent end is at least coincident with the distal tissue graft end*** and ***the first proximal stent end is at least coincident with the proximal tissue graft end*** to prevent the tissue graft from everting or folding into the passage of the first expandable stent (claim 1).

The text of the specification of the Love reference also does not teach stent tissue graft prostheses that include a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; a multilayered tissue graft construct having a distal construct end and a proximal construct end, a tubular wall and a passage extending longitudinally therethrough and disposed on said first stent; and a second expandable stent having a tubular wall and a passage extending longitudinally therethrough, said second stent being disposed over and around said construct and said first stent, and retaining said construct disposed on said first stent, wherein ***the first distal stent end is at least coincident with the distal construct end*** and ***the first proximal stent end is at least***

coincident with the proximal construct end to prevent the multilayered tissue graft from everting or folding into the passage of the first expandable stent (claim 20).

Although, the Love reference teaches vascular prostheses that include inner and outer support elements with tissue between the inner and outer support elements, there is no teaching or suggestion whatsoever in the text of the specification of the Love reference of the proximal and distal ends of a first (inner) stent (inner support element) being at least coincident with the ends of the tissue graft or with the ends of the multilayered tissue graft construct, as defined by Applicants' claims.

Also, none of the figures of Love illustrate stent tissue graft prostheses where *both*, the proximal and distal ends of the first (*inner* or inner support element) stent are coincident with the ends of the tissue graft to prevent the tissue graft from everting or

folding into the passage of the first expandable stent. For example, the top portion of the figure 1 of the Love reference does not show the end of the inner stent to be coincident with the end of the graft. Furthermore, because the prosthesis of figure 1 has a portion of the tissue cut away, in absence of specific teaching in the text of the specification of Love, one would not conclude that the ends of the tissue would have been at least coincident with the ends of the inner helical element 16.

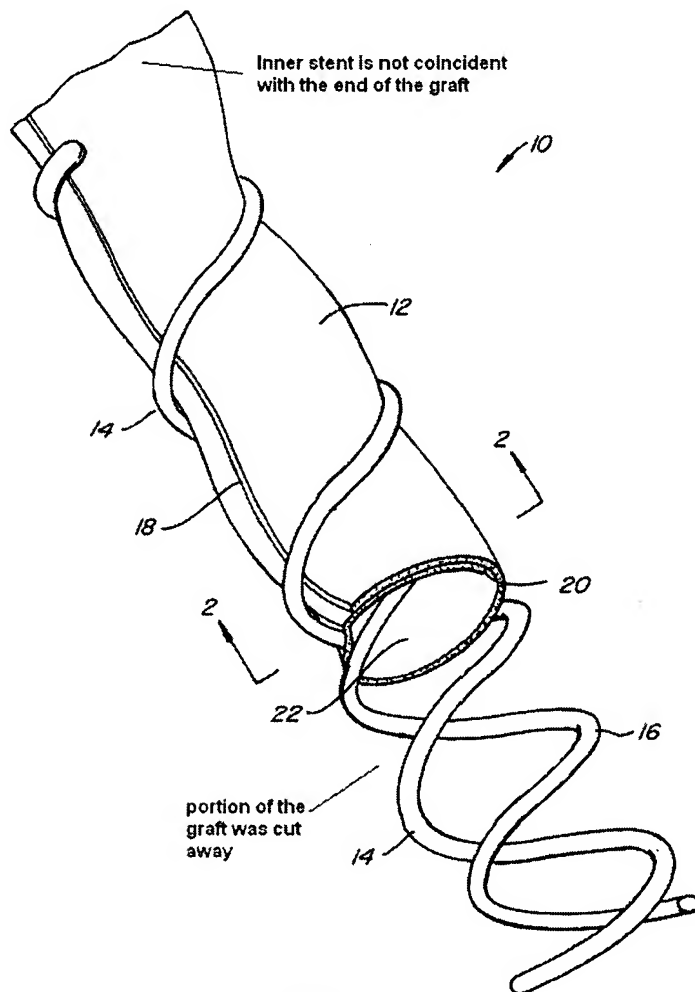
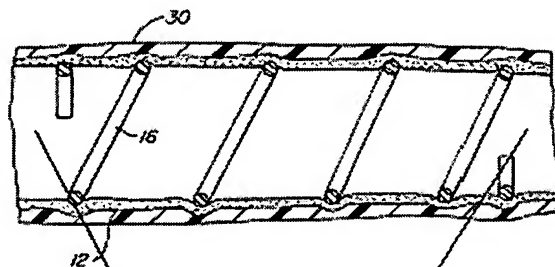


FIG. 1.

Similarly, figures 2 and 3 of Love do not show that the ends of element 14 coincide with the ends of tissue 12.

Although figure 4 of the Love reference illustrates the outer sleeve 30 coinciding with the ends of tissue 12, the *inner* helical element 16 is not shown to coincide with the ends of tissue 12. Because Applicants require the ends of the first (or *inner*) expandable stent (inner support element) to at least coincide with the ends of the tissue graft, Applicants' prostheses differ from the prosthesis illustrated in the figure 4 of Love.



Inner stent 16 is not coincident with the ends of the graft 12

Likewise, figures 5-8 of the Love reference do not show Applicants' prostheses. Rather, figures 5-8 illustrate a method of preparing the prosthesis of Love, where it is clear, especially from figures 6, 7 and 8, that both ends of the *inner* helical support element 16 do not coincide with the ends of tissue 12. In fact, it is shown in figures 7 and 8 that the tissue extends beyond one end of the inner helical support element 16.

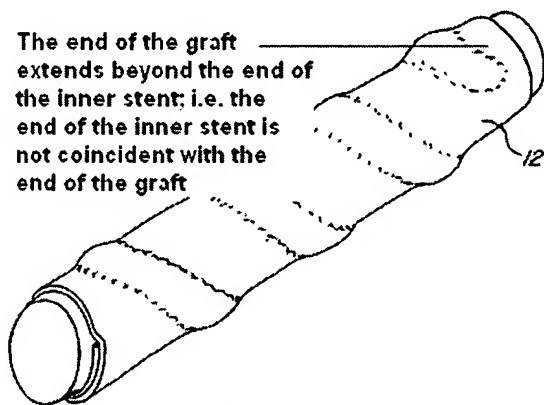


FIG. 7.

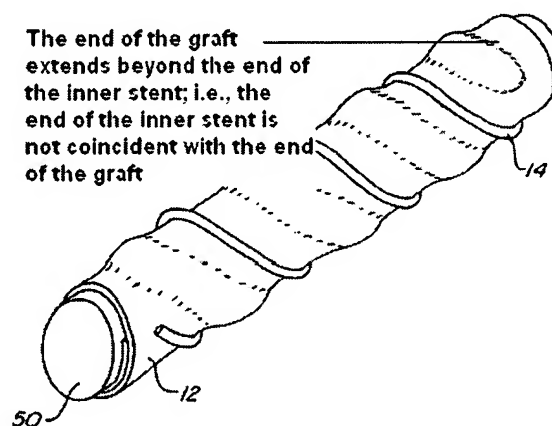
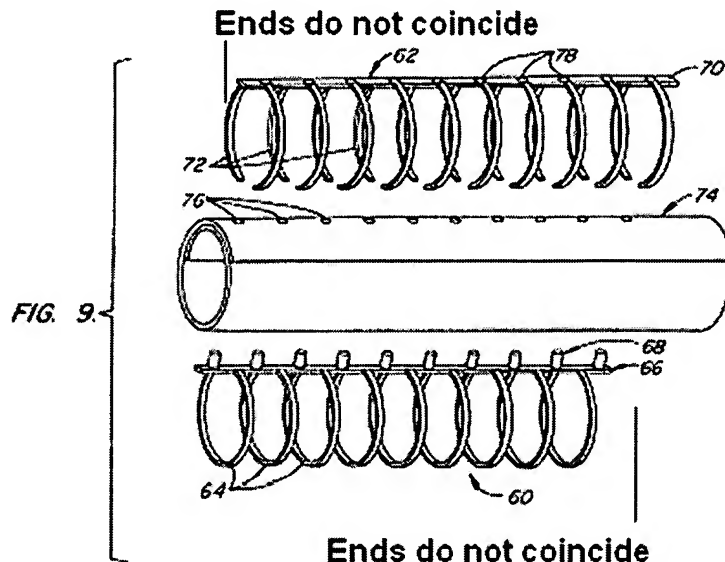


FIG. 8.

Lastly, none of the figures 9-12 illustrate the ends of the *inner* structural element coinciding with the ends of the tissue.



Because there is no teaching or suggestion whatsoever in the cited reference of both proximal and distal ends of the first (or inner) stent coinciding with the proximal and distal ends, respectively, of the tissue graft or multilayered tissue graft construct, the Section 102(b) rejection of claims 1, 2, 6, 9-11, 14, 17, 18 and 20 that was predicated on Love should be withdrawn.

Rejection under 35 U.S.C § 103 – Obviousness

The Examiner also issued a 35 U.S.C § 103(a) rejection of claims 4, 5, 7, and 8 as being unpatentable over Love in view of U.S. Pat. No. 6,358,284 B1 to Fearnot *et al.* (Fearnot *et al.*); and rejection of claims 1, 12, and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk in view of Fearnot *et al.*

Applicants disagree with the Examiner's rejections for the following reasons.

As discussed above, neither the text of the specification nor the figures of the Love reference teach, show or even suggest stent tissue graft prostheses that include a first (inner) expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; a tissue graft

having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent; and a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent, wherein *the first distal stent end is at least coincident with the distal tissue graft end and the first proximal stent end is at least coincident with the proximal tissue graft end* to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

Likewise, neither the text of the specification nor the figures of the Pinchuk reference teach or show stent tissue graft prostheses that include a *first (inner) stent with ends that are at least coincident with the ends of a tissue graft*. Although, the Examiner asserted that figures of Pinchuk clearly show that the distal and proximal ends of the stent coincide with the distal and proximal ends of the tissue graft, respectively, Applicants respectfully point out that none of the figures of Pinchuk actually illustrate stent tissue graft prostheses where both, the proximal and distal ends of the *inner* stent are coincident with the ends of the tissue graft to prevent the tissue graft from everting or folding into the passage of the first expandable stent. “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Specifically, figures 1-6 do not illustrate Applicants' prostheses. Rather, figures 1 and 2 of Pinchuk illustrate a basic stent; figures 2 and 3 illustrate a graft (textile tube); and figures 5 and 6 illustrate a stent graft (stent over graft).

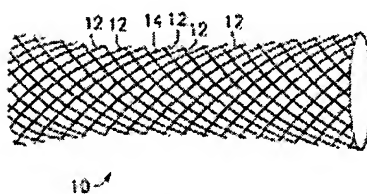


FIG. 1
PRIOR ART

Stent

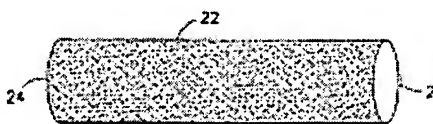


FIG. 3

Graft

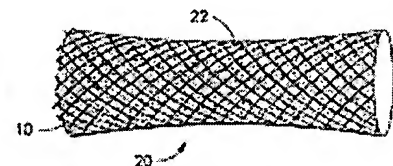
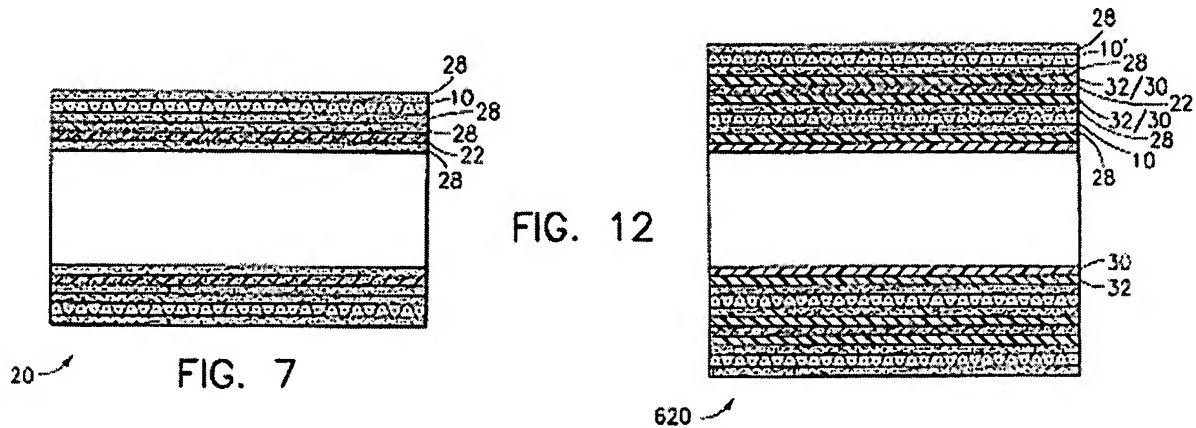


FIG. 5

Stent graft

Likewise, figures 7-12 do not show Applicants' invention. Rather, figures 7-12 of Pinchuk are cross-sectional views of various exemplary stent graft configurations and

illustrate only small *portions* of the devices. Because there is no specific teaching in the text of the specification of Pinchuk that the ends of the inner stent 10 at least coincide with the ends of the graft 22, and figures 7-12 illustrate only small *portions* of the actual devices (rather than entire device), one of skill in the art would not conclude that the figures of the Pinchuk reference teach or suggest ends of the *inner* stent coinciding with the ends of the graft.



Furthermore, figures 13-18 of Pinchuk do not teach Applicants' prostheses because none of these figures illustrate an *inner* stent and, as such these figures can not teach the ends of the *inner* stent being at least coincident with the ends of the graft.

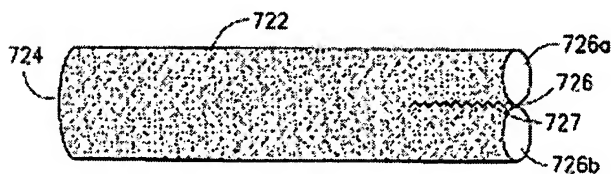


FIG. 13

No inner stent present

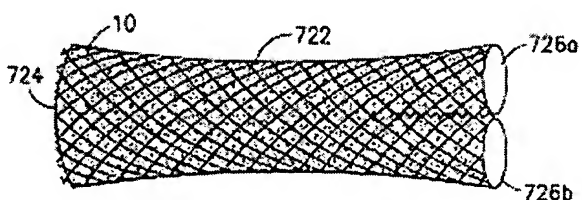


FIG. 15

No inner sent present

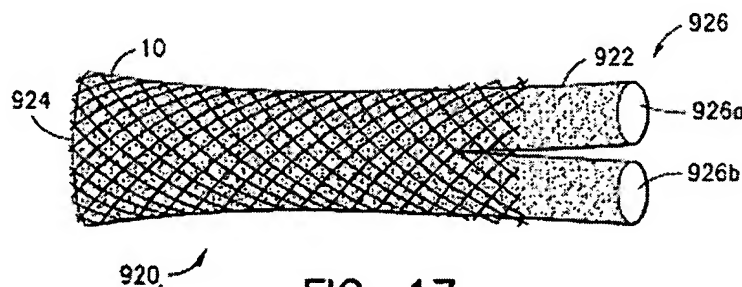


FIG. 17

No inner stent present

Although, the Pinchuk reference states that the inner stent may be included with the devices of figures 13-18, there is no teaching or suggestion whatsoever in the Pinchuk reference of ends of the *inner* stent being *at least coincident with the ends of the graft*. Clearly there is no teaching or suggestion whatsoever in the Pinchuk reference of all the elements of Applicants' claims 1, 12, and 16.

Furthermore, nothing in the Fearnot *et al.*, reference suggests modifying the prosthesis of Love or Pinchuk to include *an inner stent with ends that are at least coincident with the ends of a tissue graft* to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

Accordingly, the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious. As such, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7, and 8 are not obvious under 35 U.S.C. §103 over Love in view of Fearnot *et al.*, and claims 1, 12, and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Fearnot *et al.* Applicants request that this rejection be withdrawn.

SUMMARY

Applicants respectfully submit that present application is now in condition for allowance. If, for any reason, the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,



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